

## Food and Drug Administration, HHS

## § 882.3

882.5300 Methyl methacrylate for cranioplasty.  
882.5320 Preformed alterable cranioplasty plate.  
882.5330 Preformed nonalterable cranioplasty plate.  
882.5360 Cranioplasty plate fastener.  
882.5500 Lesion temperature monitor.  
882.5550 Central nervous system fluid shunt and components.  
882.5800 Cranial electrotherapy stimulator.  
882.5810 External functional neuromuscular stimulator.  
882.5820 Implanted cerebellar stimulator.  
882.5830 Implanted diaphragmatic/phrenic nerve stimulator.  
882.5840 Implanted intracerebral/subcortical stimulator for pain relief.  
882.5850 Implanted spinal cord stimulator for bladder evacuation.  
882.5860 Implanted neuromuscular stimulator.  
882.5870 Implanted peripheral nerve stimulator for pain relief.  
882.5880 Implanted spinal cord stimulator for pain relief.  
882.5890 Transcutaneous electrical nerve stimulator for pain relief.  
882.5900 Preformed craniostomosis strip.  
882.5910 Dura substitute.  
882.5940 Electroconvulsive therapy device.  
882.5950 Artificial embolization device.  
882.5960 Skull tongs for traction.  
882.5970 Cranial orthosis.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 44 FR 51730-51778, Sept. 4, 1979, unless otherwise noted.

### Subpart A—General Provisions

#### § 882.1 Scope.

(a) This part sets forth the classification of neurological devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a neurological device that has two or more types of uses (e.g., used both as a

diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[52 FR 17739, May 11, 1987]

#### § 882.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section, 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28,